In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-0002V

UNPUBLISHED

CECILIA ORTIZ, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: June 30, 2022 Special Processing Unit (SPU); Findings of Fact; Onset; Tdap Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT[1]

On January 2, 2019, Cecilia Ortiz filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleged that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of a tetanus, diphtheria, and pertussis vaccine ("Tdap") administered to her left shoulder on January 20, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

[1] Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

After review of the record and other filings, and for the reasons discussed below, I find that Petitioner's left shoulder pain likely began within the 48-hour timeframe for the Table claim.

I. Relevant Procedural History

Ms. Ortiz filed her petition for compensation along with medical record exhibits from January to March 2019. (ECF No. 1). Ten months later, Respondent filed a status report stating that he did not believe engaging in settlement discussions was appropriate and proposed filing his Rule 4(c) Report. (ECF No. 28).

On January 6, 2020, Respondent filed his Rule 4 (c) Report contesting entitlement in this case. (ECF No. 29). Specifically, Respondent argued that Petitioner's Table SIRVA claim failed because she had not established that the onset of her shoulder pain began within 48 hours after receiving her Tdap vaccination on January 20, 2016. Respondent's Report at 7-8. In support, Respondent noted that five days after vaccination, Petitioner presented to the office of her primary care physician, but did not report any shoulder pain or vaccine related complaints. *Id.; citing* Ex. 2 at 34-35.[3] Thereafter, Petitioner did not report shoulder pain to any medical provider for nearly five months, despite her claim that she was wearing a sling and taking Motrin daily. *Id*. at 8.

The parties subsequently filed briefing requesting a ruling on onset. My ruling is set forth below.

II. Issue

The issue presented for resolution is whether the onset of Petitioner's left shoulder pain occurred within 48 hours after vaccination, as required by the Vaccine Injury Table. 42 C.F.R. §§ 100.3(a) XIV.B. (2017) (Tdap vaccination) and 100.3(c)(10).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence.

[3] Respondent also argued that Petitioner has not established that she suffered a non-Table injury because there is insufficient evidence that the vaccine administration caused her to suffer a left shoulder injury and because she has not filed an expert report supporting her claim. *Id*. at 8.

The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). However, the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." § 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the

injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Findings of Fact

I make the following findings after a complete review of the record to include all medical records, affidavits, Respondent's Rule 4(c) Report, and any additional evidence filed. Specifically, I observe as follows:

- Ms. Ortiz received a Tdap vaccine in her left deltoid on January 20, 2016. Ex. 1 at 3-4. She was 50 years-old at the time.

- Ms. Ortiz's medical history includes a pulmonary embolism in 1991, hypertension, hyperlipidemia, obesity, and allergic rhinitis. Ex. 2 at 39-45; Ex. 7 at 34-45. There is no indication in the records of any previous left shoulder injuries.

- On January 25, 2016, five days after vaccination, Petitioner presented to her primary care physician ("PCP") complaining of feeling sluggish and eating more than usual, possibly in relation to her blood pressure medications. Ex. 2 at 34-38. There is no mention of any shoulder complaints during this visit.

- On June 14, 2016, nearly five months after vaccination, Ms. Ortiz presented to her Nurse Practitioner Bettina Raju ("NP Raju") at her PCP's office complaining of "left shoulder pain off an[d] on x6 months. States January had Tdap vaccination in left deltoid and noticed pain occurring after injection. Most pain occurs when twisting arm to put on bra with occasional numbness and tingling to extremity when in same position for extended periods of time. Denies trauma or injury. Has tried various OTC analgesics with minimal improvement and tried hot stone massage which helped for some time. Participating in yoga exercises." Ex. 2 at 30. On examination, Petitioner's left shoulder was tender to palpation and she had a reduced range of motion, although the nerve impingement test was negative. *Id*. at 31. NP Raju noted that Petitioner's left shoulder pain radiated into

her neck and arm. *Id*. Ms. Ortiz was assessed with left shoulder bursitis and prescribed home physical therapy. She was also instructed to ice the area and perform range of motion and stretching exercises. *Id*.

- On September 1, 2016, Petitioner returned to NP Raju complaining that her shoulder pain had not improved with massage therapy, acupuncture and massages. Ex. 2 at 26. Instead, her pain was worsening and radiating to the lower arm. *Id*. This time after examination, NP Raju, with Dr. Nicastro, noted that Ms. Ortiz was experiencing "moderate-severe spasms, moderate-severe tenderness and moderate-severe decreased range of motion." *Id*. at 27. An MRI of the left upper arm was ordered. *Id*. at 28.

- Ms. Ortiz underwent an MRI of her left shoulder on September 2, 2016. Ex. 2 at 51. The clinical history states "No trauma. Very sharp stabbing sensation from left shoulder joint down to hand. Pain started Jan. 2016." The impression was "Distal supraspinatus tendinopathy" and "hypertrophic changes of the acromioclavicular joint with evidence of impingement." *Id*.

- On September 8, 2016, Ms. Ortiz returned to NP Raju to review the results of her MRI. Ex. 2 at 21-23. Ms. Ortiz reported that the pain medication was helping her a little, but she was concerned because she was going out of the country on a backpacking trip and worried that her shoulder pain might worsen. *Id*. The Apley's Scratch Test (to measure reduced range of motion) was "[p]ositive for tendonitis of the rotator cuff." *Id*. at 22. NP Raju noted "moderate-severe spasms, moderate-severe tenderness and moderate decreased range of motion" and assessed "bicipital tendinitis, left shoulder." *Id*. Ms. Ortiz was referred to pain management. *Id*. She was prescribed Tramadol for pain. Ex. 2 at 23.

- On September 14, 2016, Ms. Ortiz underwent a left shoulder injection under ultrasound guidance, left cervical paraspinals, trapezius, and rhomboid trigger point injections, and a limited ultrasound evaluation of the left shoulder bursa. Ex. 8 at 2. During the evaluation, mild edema was noted in the subdeltoid bursa. *Id*. at 3.

- On October 10, 2016, Petitioner presented to Nurse Practitioner Kenneth Fuller with complaints of "persistent pain on left arm and shoulder." Ex. 2 at 16. The Apley's Scratch Test was again "[p]ositive for tendonitis of the rotator cuff." *Id*. He placed a therapy treatment order for "ice, electrical muscle stimulation, ultrasound, manipulation, physical medicine and myofascial release." *Id*. at 17-18.

- On October 12, 2016, Ms. Ortiz underwent a second left steroid injection with ultrasound guidance, left cervical paraspinals, trapezius, and rhomboid trigger point injections, and a limited ultrasound evaluation of the left shoulder bursa. Ex. 8 at 6. The same finding of edema as previously noted was stated in the report. *Id*. at 7.

- On October 24, 2016, Ms. Ortiz presented to Dr. Lacrecia Foster reporting that she had been seen by pain management and received three steroid injections. Ex. 2 at 10. Petitioner reported that she experienced some improvement but that she recently went on a backpacking trip and re-flared her shoulder. *Id*. at 10. She declined repeat injections and had put her arm in a sling to alleviate the pain. *Id*. Ms. Ortiz requested a physical therapy referral as the pain had been waking her up at night. *Id*. Dr. Foster also prescribed a muscle relaxant and Tramadol. *Id*. at 13.

- On November 18, 2016, Petitioner underwent an arthrogram of her left shoulder which showed "moderate tendinosis … involving the supraspinatus and infraspinatus tendon with a shallow low-grade partial thickness articular sided tear involving the anterior fibers of the infraspinatus tendon… 2. Partial thickness interstitial tear is noted involving the mid fibers of the subscapularis tendon… 3. Moderate degenerative changes are noted involving the posterosuperior labrum without a definite labral tear … 4. Moderate to severe arthrosis … involving the acromio clavicular joint with synovial and capsular hypertrophy. Near total effacement of the fat overlying myotendinous junction of the supraspinatus mild increasing anatomic risk for impingement." Ex. 11 at 2-3. She received an intra-articular injection of lidocaine in her left shoulder. Ex. 11 at 1.

- On December 22, 2016, Ms. Ortiz underwent surgery – a left shoulder arthroscopy, manipulation under anesthesia and lysis of adhesions. Ex. 4 at 3. The postoperative diagnosis was left shoulder adhesive capsulitis and left shoulder partial thickness supraspinatus tendon tear. *Id*. at 4. The operative report notes that when the subacromial space was visualized during surgery, "there was extensive synovitis and bursitis present within the subacromial space." *Id*. at 5. A complete bursectomy was performed. *Id*.

- On April 12, 2017, Ms. Ortiz returned to Dr. Foster, for a follow up and treatment of "left shoulder pain, cervical pain radiating to left shoulder, arm, and thoracic pain." Ex. 2 at 6. On examination, Dr. Foster noted that Petitioner was positive for cervical spine joint and nerve root injury on the left as well as for a supraspinatus injury on the left. *Id*. at 8. Dr. Foster ordered electrical muscle stimulation, ultrasound, physical medicine and myofascial release, three times per week for two weeks. Petitioner was instructed to return in two weeks. *Id.*

- The last mention of the left shoulder is during an examination on May 4, 2017, where it is noted that "bursitis of the left shoulder – stable." Ex. 7 at 8.

- In an undated letter, Claudia Bonacchi from Cla'-Bo Specialty Day Spa, stated that she provided massage services to Ms. Ortiz about 7 times between June 2017 and September 2018. Ex. 5. Ms. Bonacchi stated that during Petitioner's last session in September 2018, Ms. Ortiz "complained of acute pain under the shoulder blade and at the base of the neck." *Id.*

- No records have been filed for any treatment after December 27, 2018. Ex. 7 at 3.

- Ms. Ortiz filed an affidavit to explain the circumstances she recalled surrounding her receipt of the Tdap vaccine and to explain her delay in seeking medical treatment for her shoulder. Ex. 12 at 1. She stated that on January 20, 2016, "I was sitting down, and the vaccine administrator was standing. I thought it was a little high up my arm towards my shoulder compared to flu shots I received in the past. Immediately following receipt of the Tdap vaccine, I felt pain in my left shoulder… but I figured it was normal after a shot so I did not tell anyone." Ms. Ortiz stated that she delayed seeking treatment because she "did not think I needed a doctor until the pain was interfering with my sleep and at work the pain was there all day." She stated that she did not mention the shoulder pain at her January 25, 2016 visit because "I assumed I was just sore, and didn't think much of it at the time." Ms. Ortiz stated that she did not return to be seen for shoulder pain "because I typically am one to avoid doctors. Instead, I took over the counter pain medication, used essential oils, and used a sling and other supports because my elbow, wrist and hand hurt from the radiating pain." *Id*. at 2, ¶7. It was only during an incident where her cousin bumped her arm and the pain was so severe that "it took my breath away for a few minutes," that Ms. Ortiz decided that she needed to seek medical care.

V. Ruling Regarding Onset

After a careful review of the record, I find that the evidence preponderates (albeit barely) in Petitioner's favor on the disputed onset issue.

There is no dispute that Ms. Ortiz did not suffer from any left shoulder symptoms prior to receiving the Tdap vaccine in January 2016. And the record corroborates the fact of subsequent injury – even though, admittedly, there are no close-in-time treatment records. It is true that the one close-in-time record (from when Petitioner saw her physician within a week of receiving the vaccine) does not memorialize a report of pain. But this is not inconsistent with what other Program petitioners experience, based on the

assumption that their pain is likely transitory. Indeed, many SIRVA cases feature medical record notations from physicians recommending that a patient wait a period of time after vaccination to allow time for the shoulder pain to fade before seeking treatment. Subsequent records in this case, however, all corroborate the injury and onset, and the Vaccine Act expressly does not obligate claimants to prove onset issues with evidence from *within* the alleged timeframe in any event. Section 13(b)(2).

The sworn testimony of Petitioner on the onset question is also credible and in agreement with the contemporaneously created treatment records. I do not agree with Respondent's argument that Ms. Ortiz's two affidavits are inconsistent and that the "contemporaneous medical records conflicts with petitioner's recollection." Respondent's Brief at 8. The fact that Ms. Ortiz first averred that she felt pain immediately after vaccination does not necessarily conflict with the statement in her second affidavit where she states that the vaccine area was "sore" and "little by little, the soreness became pain." Pain threshold is a subjective perception. Soreness may be perceived as pain by some individuals, but not by others. In any event, Respondent's argument on this point is weak and unpersuasive.

Another factor that weighs in favor of a finding of 48-hour onset of left shoulder pain is the absence of any statement or record that places the onset of Ms. Ortiz's left shoulder pain *outside* the 48-hour window. By contrast, there are at least two records where Ms. Ortiz reports that her pain began on the day of vaccination. *See e.g.*, Ex. 2 at 30-33 (regarding pain in her arm "L shoulder pain off/on x 6 months. States in January had Tdap vaccination in L deltoid and noticed pain occurring after injection."); Ex. 2 at 51 ("sharp stabbing sensation from L shoulder joint down to hand. Pain started Jan 2016").

Unquestionably, the five-month records gap from vaccination to the first efforts to treat Ms. Ortiz's alleged shoulder pain undermines Petitioner's case. As Respondent argues, it is reasonable to expect that the average Program claimant might seek medical treatment sooner if in fact the person was experiencing sudden post-vaccination pain. However, as noted above, claimants may often misperceive the extent of their shoulder injury, or downplay its significance, leading them to delay treatment. *See, e.g.*, *Williams v. Sec'y of Health & Human Servs.*, No. 17-830V, 2019 WL 1040410, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2019) (noting a delay in seeking treatment for five-and-a-half months because petitioner underestimated the severity of her shoulder injury); *Tenneson v. Sec'y of Health & Human Servs*., No. 16-1664V, 2018 WL 3083140, at *5 (Fed. Cl. Spec. Mstr. March 30, 2018), *review denied*, 142 Fed. Cl. 329 (2019) (finding a 48-hour onset of shoulder pain despite a nearly six-month delay in seeking treatment); *Marino v. Sec'y of Health & Human Servs.,* No. 16-622V, 2018 WL 2224736, at *2 (Fed. Cl. Spec. Mstr. Mar. 26, 2018) (noting a delay in seeking treatment for several months due to petitioner's work schedule and difficulty making appointments); *Knauss v. Sec'y of Health & Human Servs.*,

No. 16-1372V, 2018 WL 3432906 (Fed. Cl. Spec. Mstr. May 23, 2018) (noting a three-month delay in seeking treatment).

Here, as in other cases, Respondent argues that a special master cannot rely on the statements of the petitioner alone regarding a key element like onset. *See e.g., Juno v. Sec'y of Health & Human Servs.*, No. 18-643, 2021 WL 4782691, at * 5 (Fed. Cl. Spec. Mstr. Sept. 13, 2021). But the Federal Circuit has expressly recognized that witness testimony on issues pertaining to fact matters *can* be proven by reliance on testimonial evidence (even if the evidence must be weighed against the records themselves, which continue to have evidentiary significance). *Kirby*, 997 F.3d at 1383. Respondent has not identified any inconsistencies or discrepancies in the medical records. And in this case, the relevant witness statements are not the only evidence in favor of an onset finding consistent with a Table SIRVA claim.

At bottom, the evidence preponderates, although weakly, in favor of a determination that onset began in 48 hours of vaccination. Of course, the fact of Petitioner's delay will bear on any damages to be awarded in this case, since it either underscores a SIRVA mild enough to be tolerated for a long time, or establishes Petitioner's own contributions to severity.[4] But these considerations are separate from whether onset did happen as Petitioner alleges.

VI. Scheduling Order

Given my findings of fact regarding onset of Ms. Ortiz's left shoulder pain, Respondent should evaluate and provide his current position regarding the merits of Petitioner's case.

Accordingly, the following is ORDERED:

(1) By <u>Monday, August 5, 2022,</u> Petitioner shall file all updated medical records.

[4] This appears to be a classic example of an individual holding off on medical treatment for what started as mild shoulder pain, but progressed and worsened to a severe condition – thereby exacerbating the condition. Guarding or non-use of the shoulder can lead to adhesive capsulitis or frozen shoulder, and Petitioner's non-use may have also led to neck and shoulder pain because she began shifting the use of her left arm to other parts of the body. The backpacking trip she took in October 2016 also likely exacerbated her pain and symptoms. Due to the lack of care early on, what may have otherwise been a mild shoulder injury progressed to a serious injury requiring surgical intervention.

(2) Respondent shall file, by no later than Monday, August 29, 2022, an amended Rule 4(c) Report reflecting Respondent's position in light of the above fact-finding.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master